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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,127	10/16/2001	Steven Curtis Zicker	6493-02-HL	3786

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EXAMINER	
BAEK, BONG-SOOK	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/978,127	ZICKER ET AL.	
	Examiner	Art Unit	
	BONG-SOOK BAEK	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39 and 44-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39 and 44-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of claims

Applicants' arguments and declaration under 37 C.F.R§ 1.131, filed on November 13, 2008, have been fully considered but they are moot in view of new ground of rejections. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application. Responses are limited to Applicants' arguments relevant to either reiterated or newly applied rejections. Claims 39 and 44-47 are under examination in the instant office action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 39 is rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,232,346.

US Patent 6,232,346 teaches a method of medical treatment of a disease, disorder or abnormal physical state in a mammal such as functional deterioration associated with ageing, wherein the method comprising administering to a mammal an effective amount of a nutritional supplement comprising L-carnitine, coenzyme Q10 (ubiquinone) and taurine in combination

with vitamin E, vitamin C, cysteine, selenium, thiamine, and creatine (abstract, example 1, and claim 1). It further teaches that the mammal is selected from the group consisting of a human, a dog (canine), a cat (feline), and horse (claim 7). In addition, it disclosed a liquid supplement containing about: 2.7 grams of taurine, 2.7 grams of carnitine (11000 ppm), 135 mg coenzyme Q10 plus antioxidant vitamins such as 400 IU vitamin E (800 ppm) and 250 mg Vitamin C (1000 ppm) and 1.75 grams of creatine per 250 milliliters (column 17 lines 24-28).

Although the instant claims do not recite the other ingredients such as coenzyme Q10 (ubiquinone) and taurine, which are recited in the reference, the instant claims recite the open language "comprising", which does not exclude additional unrecited elements (see MPEP 2111.03).

The reference does not specifically define that treating functional deterioration associated with ageing encompasses “inhibiting the loss of learning ability or increasing the learning ability”, however it would be inherent outcomes since the reference teaches the same method step comprising administering the same composition to the same patient population as the instant claim. It is noted that products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). When the claimed and prior art products are identical or substantially identical in structure or composition, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977).

Claim Rejection(s)—35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 39, 44-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,232,346 in view of Hagen *et al.* (FASEB J, 13:411-418, Feb. 1999).

US Patent 6,232,346 teaches a method of medical treatment of a disease, disorder or abnormal physical state in a mammal such as functional deterioration associated with ageing, wherein the method comprising administering to a mammal an effective amount of a nutritional supplement comprising L-carnitine, coenzyme Q10 (ubiquinone) and taurine in combination with vitamin E, vitamin C, cysteine, selenium, thiamine, and creatine (abstract, example 1, and claim 1). It further teaches that the mammal is selected from the group consisting of a human, a dog (canine), a cat (feline), and horse (claim 7). In addition, it disclosed a liquid supplement

containing about: 2.7 grams of taurine, 2.7 grams of carnitine (11000 ppm), 135 mg coenzyme Q10 plus antioxidant vitamins such as 400 IU vitamin E (800 ppm) and 250 mg vitamin C (1000 ppm) and 1.75 grams of creatine per 250 milliliters (column 17 lines 24-28).

The reference does not specifically define that treating functional deterioration associated with ageing encompasses "inhibiting the loss of learning ability or increasing the learning ability", however it would be expected outcomes since the reference teaches the same method step comprising administering the same composition to the same patient population as the instant claim. It is noted that products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). When the claimed and prior art products are identical or substantially identical in structure or composition, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977).

The reference differs from the instant claims insofar as it does not specifically teach α-lipoic acid and its dosage amount.

Hagen *et al.* discloses feeding α-lipoic acid (0.5 % w/w = 5000 ppm) to old rats for 2 weeks restores mitochondrial function, lowers oxidants to the level of a young rats and increase ambulatory activity (abstract). It further teaches that lipoic acid supplementation improves indices of metabolic activity as well as lowers oxidative stress and damage evident in aging (abstract).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the method of US Patent 6,232,346 to specifically administer to the aged dog or cat L-carnitine and vitamin E, C in combination with α- lipoic acid because one of ordinary skill in the art would reasonably expect the combination of these anti-oxidant compounds to inhibit oxidative stress associated with aging. Since L-carnitine, Vitamin E, C, and α- lipoic acid are taught to be effective for improving age-related functional deterioration and lowing oxidative stress, one of ordinary skill in the art would reasonably expect the combination of those anti-oxidants not only to inhibit oxidative stress associated with aging but also to counteract age-related loss of learning ability and improve mental acuity in the aged cats and dogs. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition to be used for the very same purpose…..The idea of combining them flow logically from their having been individually taught in the prior art." See *In re Kerkhoven*, 626 F. 2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980)

With regard to the claimed dosage amounts, since US Patent 6,232,346 and Hagen *et al.* disclosed effective amounts, i.e. dosage amounts, are necessary to the treatment of age-related functional deterioration and oxidative stress, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the effective amounts taught by US Patent 6,232,346 and Hagen *et al.* such that the dosage amounts of the carnitine, vitamin E, vitamin C and alpha-lipoic acid are effective to inhibit oxidative stress or symptoms associated with aging in animals, thereby improving mental acuity and inhibiting age-related memory loss.

In addition, it is well-established that merely selecting proportions and ranges is not patentable absent a showing of criticality. *In re Becket*, 33 USPQ 33; *In re Russell*, 169 USPQ 426. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.")

Claims 39, 44-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,915,912 (issue date: 6/29/1999) in view of Shigenaga *et al*. (Proc Natl Acad Sci USA, 91:10771-10778, 1994).

US Patent 5,915,912 teaches a method for increasing the metabolic rate of aged cells without a concomitant increase in metabolic production of reactive oxygen species, comprising orally administering to a mammalian host an effective dosage of at least about 10 mg/kg (10 ppm) host/day of a carnitine and at least about 10 mg/kg (10 ppm) host/day of a mitochondrially active antioxidant such as lipoic acid (abstract). It further teaches that two reagents given to old animals, restored all three mitochondrial functions and reversed several gross indicia of aging, including activity, muscle tone, coat appearance and kidney morphology (column 1, lines 44-47). Also, it disclose that mitochondrially active antioxidants include vitamins (especially C, E, B and D), glutathione, N-acetyl cysteine, lipoic acid, which have been used variously as human nutritional supplements and in dietary prophylaxis and therapy (column 2, lines 1-5).

The reference differs from the instant claims insofar as it does not specifically teach the combination of four drugs, e.g. lipoic acid and carnitine with vitamin E and vitamin C and the specific dosage amount recited in claims 46-47. Also, it does not specifically state that the mammalian host is a companion pet such as a canine (dog) or feline (cat).

Shigenaga *et al*. teaches that age-associated accumulation of mitochondurial deficits due to oxidative damage is likely to be a major contributor to cellular, tissue, and organismal aging (abstract). It further teaches that sustained damage inflicted by endogenously produced oxidants is the likely cause of the age-related deficits in mitochondrial function and this decline is associated with a generalized physiological decline that is common to all aging organism (p, 10771, column 1 , para 1). In addition, it teaches that oxidants and mitochondrial deficits are associated with increased neuronal loss through excitotoxic mechanism and the attrition of a sufficient number of neurons can lead to age-associated disability and loss of various physiological functions such as receptor-mediated signal transduction (p, 10776, column 2, para 2), and decreased receptor number and less efficient signal transduction is responsible for a marked decline in cognitive and motor function (p10776, column 2, para 3).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the method of US Patent 5,915,912 by adding more mitochondrially active antioxidants such as vitamin E and C to the combination of L-carnitine and α- lipoic acid taught by US Patent 5,915,912 for inhibiting the loss of learning ability or increasing the learning ability with reasonable expectation of success because one of ordinary skill in the art would reasonably expect the combination of these anti-oxidant compounds to synergistically inhibit oxidative stress and restore mitochondrial function, which are associated with physiological

decline including cognitive and motor function as taught by Shigenaga *et al*. Since carnitine and mitochondrially active antioxidants such as lipoic acid, vitamin E and vitamin C as are taught to be effective for restoring age-related functional deterioration of mitochondria and lowering oxidative stress as taught by US Patent 5,915,912, one of ordinary skill in the art would reasonably expect the combination of those anti-oxidants not only to inhibit oxidative stress and mitochondrial dysfunction associated with aging but also to counteract physiological decline such as age-related loss of learning ability and improve mental acuity in the aged cats and dogs. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition to be used for the very same purpose…..The idea of combining them flow logically from their having been individually taught in the prior art." See *In re Kerkhoven*, 626 F. 2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

With regard to "aged dog or cat", since the composition of the prior art is effective for mammalian hosts, it would be obvious to try the composition to any animals including dogs and cats on the expectation that the composition would be similarity effective to any species of mammals since the age-related deficits in mitochondrial function is associated with a generalized physiological decline that is common to all aging organism as taught by Shigenaga *et al*.

With regard to the claimed dosage amounts, since US Patent 5,915,912 disclosed effective amounts, i.e. dosage amounts, are necessary to the treatment of age-related functional deterioration of mitochondria and oxidative stress, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the effective amounts of US

Patent 5,915,912 such that the dosage amounts of the carnitine, vitamin E, vitamin C and lipoic acid are effective to inhibit oxidative stress or symptoms associated with aging in animals, thereby improving mental acuity and inhibiting age-related memory loss. In addition, it is well-established that merely selecting proportions and ranges is not patentable absent a showing of criticality. *In re Becket*, 33 USPQ 33; *In re Russell*, 169 USPQ 426. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.")

Examiner's notes

Applicants are advised to reword from "ppm" in claim 46-47 to "part per million" for clarification.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BONG-SOOK BAEK whose telephone number is 571-270-5863. The examiner can normally be reached 9:00-6:00 Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian-Yong S Kwon/
Primary Examiner, Art Unit 1614
/Bbs/

BONG-SOOK BAEK
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